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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,810

11/12/2003

Robert S. Davidson

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,810	Applicant(s) DAVIDSON ET AL.	
	Examiner JAKE M. VU	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-88 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 50-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-49 and 84-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 01/28/2008; and Information Disclosure Statement filed on 01/28/2008.

- Claims 1, 3, 6, 28, 29, and 42 have been amended.
- Claims 4 and 5 have been cancelled.
- Claims 84-88 have been added.
- Claims 1-3 and 6-88 are pending in the instant application.
- Claims 2 and 50-83 have been previously withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 87 and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 3 recite the newly amended limitation of "bilayer", claim 87 recites the newly amended limitation of "2 to 4% (w/w) and the powder matrix coating prevents the bilayer composition from sticking to another bilayer composition", and claim 88 recites the newly amended limitation of "plurality of bilayer compositions" and "2 to 4%

(w/w) and the powder matrix coating prevents a first bilayer composition from sticking to a second bilayer composition"; however, the specification as-filed and incorporated US Patent 5,948,430 do not provide a written description or set forth the metes and bounds of this phrase. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

Claim Rejections - 35 USC § 102

Claims 1, 3 and 28 are rejected under 35 U.S. 102(e) as being anticipated by BARKALOW et al (US 2004/0096569) **are withdrawn** in view of Applicant's amendment.

Claims 1, 3, 6, 7, 16, 17, 20-32, 36-39, 42-45, 84, and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 98/20863; which is also published as US 6,783,768) **are maintained** for reasons of record in the previous office action filed on 10/05/2007.

Note, BROWN teaches using a polyalcohol softener, such as propylene glycol (see col. 13, line 43) and PEG (see col. 16, line 7), which is polyethylene glycol. Additionally, BROWN teaches using a plasticizer (see col. 16, line 8), which would read on a softener.

Note, the powder matrix coating prevents the bilayer composition from sticking to another bilayer composition is inherent to the prior art's powder matrix since it has the same ingredients as claimed by Applicant.

Applicant argues that BROWN does not teach using at least one softener. The Examiner finds this argument unpersuasive, because BROWN teaches using a polyalcohol softener, such as propylene glycol (see col. 13, line 43) and PEG (see col. 16, line 7), which is polyethylene glycol. Additionally, BROWN teaches using a plasticizer (see col. 16, line 8), which would read on a softener.

Claim Rejections - 35 USC § 103

Claims 1, 3, 6-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN et al (WO 98/20863; which is also published as US 6,783,768) in view of BARKALOW et al (US 2004/0096569) **are maintained** for reasons of record in the previous office action filed on 10/05/2007 and as discussed below for the newly added claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6-49 and 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN et al (WO 98/20863; which is also published as US 6,783,768) in view of BARKALOW et al (US 2004/0096569)

As discussed in the previous office action, BROWN teaches a composition comprised of: a film layer (see US 6,783,768 at col. 8, line 50); a coating (see col. 8, line 47-50) on at least one outer surface comprise a medicant, such as diltiazem (see col. 11, line 6). Additional disclosures include: coating material in the form of powder material (see col. 3, line 38), which reads on powder matrix; medicant can be in any layer (see col. 55-63); mucosa adherent, such as hydroxypropyl cellulose (see col. 11, line 52-53); bulking agent, such as xylitol (see col. 11, line 4); thickness less than 1mm (see col. 8, line 25-28); Eudragit RS (see col. 11, line 51), which is an acrylic acid copolymer; flow agents, Aerosil 200 (see col. 11, line 56); powder coating has the advantage of reduction in waste and improved coating efficiency (see col. 2, line 41-44). BROWN further teaches using a polyalcohol softener, such as propylene glycol (see col. 13, line 43) and PEG (see col. 16, line 7), which is polyethylene glycol. Additionally, BROWN teaches using a plasticizer (see col. 16, line 8), which would read on a softener.

BROWN does not teach using pullulan; carrageenan; stearic acid; carboxymethylcellulose; lipid; starch; medicant, which is a cough curing agent, such as menthol; sweetener; talc and glycerol.

BARKALOW teaches a composition comprised of: multiple film layers, such as two layers (see [0092]) which would read on a film layer and a coating on at least one outer surface, since the coating would be an additional layer. Additional disclosure includes: a cough-curing agent, such as menthol (see [0028]); powder coating (see [0065]); pullulan (see [0042]); carrageenan (see [0024]); stearic acid (see [0089]), which is a lipid; carboxymethylcellulose (see [0024]); starch (see [0087]); sweetener (see [0097]); talc (see [0088]); acrylic copolymer (see [0087]) and 3% of glycerin (see [0026], [0089], [0106] Ex. 4, and claim 15), which is glycerol. These are common ingredients in the art of edible film (see Applicant's provisional application 60/426598). Additional disclosure include: plasticizers, such as glycerin, which is glycerol, polyethylene glycol and propylene glycol (see [0026]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate pullulan, carrageenan, stearic acid; carboxymethylcellulose, starch, menthol, sweetener, talc, and 3% of glycerin into BROWN's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because these are commonly used ingredients in the art of edible film and BARKALOW suggested powder coating can be used [see 0065]), and reasonably would have expected success because both references are in the same filed on endeavor.

Note, the powder matrix coating prevents the bilayer composition from sticking to another bilayer composition is inherent to the prior art's powder matrix since it has the same ingredients as claimed by Applicant.

Applicant argues that BARKALOW does not teach a powder matrix coating. The Examiner finds this argument unpersuasive, because BARKALOW is used as a secondary reference. The primary reference, BROWN, teaches a powder matrix coating.

Applicant argues that BARKALOW does not suggest the use of a powder coating. The Examiner finds this argument moot and unpersuasive, because BARKALOW teaches coating techniques such as powder coating (see [0065]) and the BROWN reference teaches powder coating.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jake M. Vu, PharmD, JD
Art Unit 1618